

REMARKS

Favorable reconsideration and allowance of this application are requested.

1. Interview Substance

The Examiner's Interview Summary dated February 21, 2008 completely and adequately sets forth the substance of the telephonic communication with the Examiner on February 8, 2008. Accordingly, further comment thereon appears unnecessary. Applicants' undersigned representative appreciatively notes that the record will be corrected so as to accurately reflect the priority date to which the subject application is in fact entitled, namely the 27 March 2003 filing date of EP 03007009.8.

2. Discussion of Amendments

By way of the amendment instructions above, pending claims 12-20 directed toward a patentably distinct invention non-elected for prosecution herein have been cancelled. Cancellation of such non-elected claims has however been effected without prejudice to the applicants' rights under 35 USC §121.

Pending independent claim 21 has been revised so as to emphasize the process steps employed to obtain the cross-linked beadlet. Support for such limitations can be found in the originally filed specification on page 1, second full paragraph, page 2, lines 27-28, page 4, lines 3-9 and lines 27-29 as well as original claims 1-8 (which constitute their own "disclosure"). Claim 22 has been revised so as to be dependent from claim 21. Claim 23 remains as presented with the Preliminary Amendment dated July 13, 2005.

The embedded ranges in the claims have also be resolved, with the narrower range now being present in new claim 24.

Therefore, following entry of this amendment, claims 21-24 will remain pending herein for which favorable reconsideration and allowance are requested.

An amended title commensurate with the claimed subject matter herein has also been presented.

3. Response to Abstract Objection

The Abstract has been revised per the amendment instructions above so as to obviate the objection noted by the Examiner.

4. Response to 35 USC §112 Rejection and Claim Objection

The amendments to claim 21 so as to provide antecedent basis for the term "core region" and the deletion of the embedded preferred range therefrom are believed to address the rejection advanced under 35 USC § 112, second paragraph.

Claim 22 has also been amended so as to obviate the lack of clarity helpfully noted by the Examiner with respect to the recited amounts of vitamins A and D.

Reconsideration and withdrawal of the assertion that the phrase "surface region" is statutorily indefinite is in order. In this regard, it is of course axiomatic that an applicant can be his own lexicographer. (MPEP § 2173.20). Thus, the fact that the present applicants employed the phrase "surface" as the name of the recited beadlet component which surrounds the "core region" cannot possibly invoke indefiniteness within the purview of 35 USC §112, second paragraph.¹ Thus, while the Office may examine claim components in their broadest reasonable interpretation, it cannot assert indefiniteness for a claim component under 35 USC §112, second paragraph where,

¹ A claim may not be rejected solely because of the type of language used to define the subject matter for which patent protection is sought. *In re Swinehart*, 160 USPQ 226 (CCPA 1971).

like here, the language is entirely definite. To be sure, the "surface region" of the claimed beadlet is that structural part of the beadlet which surrounds the "core region".

Withdrawal of the rejection advanced against claims 21 and 22 under 35 USC §112, second paragraph is therefore in order.

5. Response to 35 USC §102(b) Rejections

Claim 21 attracted a rejection under 35 USC §102(b) as allegedly anticipated by Scialpi (USP 4,670,247). Claims 22-23 attracted a rejection under 35 USC §102(b) as allegedly anticipated by Borenstein et al (USP 5,043,170). Applicants suggest that the pending claims are patentable over such references.

In this regard, applicant notes that the steps of converting an emulsion containing the active ingredients into a dry coating and heating such dry particulate (so that the gelatine and the sugar of the matrix are reacted together (Maillard reaction)) are very important for the final distribution of the active ingredients in the beadlet – i.e., so as to ensure that less than 10% (preferably less than 5%) of the active ingredient content is in the surface region. Thus, these process steps which impart the low active ingredient content in the surface region include the following:

- forming an emulsion containing the active ingredients, an emulsifier and a reducing sugar, (see page 2, lines 25-26 of the original disclosure)
- converting the emulsion to a dry particulate form by coating the emulsion droplets with a finely dispersed powder selected from the group consisting of polysaccharides such as starch and modified starch, calcium silicate or of a mixture of calcium silicate with one of the following mixture components: microcrystalline cellulose, magnesium silicate, magnesium oxide, stearic acid, calcium stearate, magnesium stearate, hydrophilic silicic acid and kaolin. (see page 2, lines 27-28; and page 4, lines 3-9 of the original disclosure),

- and optionally drying the coating, (see page 4, lines 27-29 of the original disclosure) and
- heat treating the dry particulate form at a temperature in the range of from 90°C to 140°C for a time period of from 30 seconds to 30 minutes or from 1 minute to 10 minutes or from 3 minutes to 7 minutes.(see page 1, second paragraph of the original disclosure).

These attributes of the presently claimed invention are not suggested or taught by either Scialpi or Borenstein et al. As such, withdrawal of the rejection advanced under 35 USC §102(b) is in order.

6. Fee Authorization

The Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, in the fee(s) filed, or asserted to be filed, or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Account No. 14-1140.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: /Bryan H. Davidson/
Bryan H. Davidson
Reg. No. 30,251

BHD:dlb
901 North Glebe Road, 11th Floor
Arlington, VA 22203-1808
Telephone: (703) 816-4000
Facsimile: (703) 816-4100